FDA Approves Incivek (Telaprevir), Second New Hep C Drug

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The U.S. Food and Drug Administration (FDA) has approved a new hepatitis C virus (HCV) treatment called Incivek (telaprevir). The drug, which is by Vertex Pharmaceuticals and is targeted to people with the difficult-to-treat HCV genotype 1, marks the second in a new class of HCV drugs, called protease inhibitors, to be approved this month.

Nearly 70 percent of the estimated 3.2 million people in the United States infected with chronic HCV have the difficult-to-treat genotype 1. For them, the standard course of treatment with pegylated interferon combined with ribavirin means enduring up to 44 weeks of grueling treatment that frequently causes serious side effects—with only about a 50 percent chance that they will achieve what most experts call a cure for the disease. For people with the more rare genoytpes 2 or 3, response rates are much higher and the course of treatment is typically shorter.

In three Phase III studies involving 2,250 people, adding 12 weeks of Incivek to standard HCV therapy substantially increased the percentage of people who achieved a sustained virological response (SVR), which means maintaining an undetectable HCV viral load for at least six weeks after completing treatment. Most people consider those who've achieved an SVR to be cured for all practical purposes.

"With the approval of Incivek, there are now two important new treatment options for hepatitis C that offer a greater chance at a cure for some patients with this serious condition," said Edward Cox, MD, MPH, director of the Office of Antimicrobial Products at the FDA's Center for Drug Evaluation and Research. "The availability of new therapies that significantly increase responses while potentially decreasing the overall duration of treatment is a major step forward in the battle against chronic hepatitis C infection."

Incivek must be taken three times per day with food. The most common side effects from the drug were rash, anemia, nausea and headaches. Though most people experienced only a mild rash, a few discontinued treatment because of it and several people in the studies developed a much more serious reaction called Stevens-Johnson syndrome, which usually requires hospitalization. People taking Incivek also sometimes experienced a bad taste in the mouth, and itchiness and irritation of the anus.

According to a Vertex press release, adding Incivek to standard therapy boosted cure rates from 46 to 79 percent in people who'd never taken HCV treatment before. In those who'd taken standard treatment in the past, and who'd either never responded to it or initially responded and then relapsed, adding Incivek increased the chance of a cure by up to six times. Also of note: Nearly 60 percent of people who took Incivek have such a good early response that they will be able to cut the duration of their treatment in half—from 48 weeks to just 24 weeks.

The FDA recommended that people have their HCV levels tested after 12 weeks of therapy that includes both Incivek and standard therapy. If they have undetectable HCV levels, then they continue standard therapy without Incivek for just 12 more weeks. If they don't have undetectable HCV levels, however, they must continue taking standard treatment for an additional 36 weeks. This course of treatment is recommended regardless of a person's earlier HCV treatment history.
